REMARKS

Formal Matters

Original Claims 1-19 are all the claims currently pending in the present application.

Information Disclosure Statement. With the current Office Action, the Examiner returns an initialed copy of the PTO-Form 1449 filed with Applicants' IDS of December 3, 2003. Applicants note, however, that the Examiner has failed to sign and date this form. Therefore, the Examiner is respectfully requested to return a signed, dated, and initialed copy of this form with the next Office communication.

Specification and Figures

Specification and Figures 6A-6C. The specification and new Figures 6A-6C are objected to under 35 U.S.C. § 132 for allegedly introducing new matter into the disclosure.

In response, Applicants note that Figures 6A-6C, submitted with the Preliminary Amendment of July 28, 2004 are exact duplicates (except larger) of the top, middle, and lower panels of original Figure 6, filed with the original Application on September 12, 2003, which were accorded informality for having a line quality too light to adequately reproduce.

Further, Applicants submit that Figures 6A-6C are fully supported in the body of the original specification at page 7, lines 6-8 and page 13, lines 4-12.

Therefore, in view of the above, Applicants respectfully request that the §132 objection to the specification and figures be reconsidered and withdrawn.

Figures. The drawings stand objected to under 37 C.F.R. § 1.83(a) for failure to show every feature of the invention specified in the clams. Specifically, the Examiner notes that the peripheral portion and the one or more haptics must be illustrated in the figures.

With this Amendment, Applicants add new Figure 7, as shown, which illustrates both the peripheral portion and the haptics. This figure is originally supported in the specification at least at page 7, lines 25-31, page 8, lines 6-24, and page 10, lines 14-18. No new matter is added.

In view of newly-added Figure 7, the Examiner is respectfully requested to reconsider and withdraw the §1.83(a) objection to the figures.

Claims 1-4 and 12-18 over Portney

Claims 1-4 and 12-18 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Portney, U.S. Patent Publication No. 2003/0199976 ("Portney"). Applicants respectfully traverse this rejection.

The Examiner asserts that Portney teaches an intraocular lens with anterior and posterior surfaces defining a visually transparent lens (IOL) optic extending from the anterior to the posterior surface. Further, the Examiner asserts that Portney discloses an IOL having a peripheral portion outside the central lens optic, where the optical properties of the peripheral portion are such that oblique incident light focusing on the peripheral portion is diminished or refracted laterally or anteriorly as opposed to posteriorly.

First, Applicants note that the Examiner is incorrect in stating that the lens of Portney has a peripheral portion located outside of the central lens optic. The lens of Portney has a peripheral transition zone that separates central and peripheral "imaging zones" of the lens. Accordingly,

the peripheral zone of the Portney lens, which is also an imaging zone, is still part of the central lens optic.

Further the Examiner is incorrect in stating that the Portney lens prevents oblique incident light from passing posteriorly into the eye. As can be seen from Figure 9, while the transition zone of the Portney lens does indeed refract oblique incident light, it is still possible for the refracted light to travel in a posterior direction.

The claims of the Portney citation refer mostly to "direct glare" "from a centrally located source of light." Portney claim 16 refers to "indirect glare created by a peripherally located source of light impinging on the optic on a substantial width of said transition zone in an individual's eye..." However, there is no indication as to how "peripheral" this light source actually is. In Portney's only publication[1] of which Applicants are aware, there is some discussion relating to this point. The specified angle of the glare is from a light source at 35 degrees from the axia, which the authors state is "consistent with nighttime glare conditions. Preliminary ray trace analysis indicated that a 35 degree angle maximized the intensity of the reflected glare image."

This differs from the angle of incidence of light used to obtain focusing and avoid dysphotopic effects in the present application, which is only over a relatively small rather than wide area of the lens of 71-89 degrees.[2]

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[1] *See attached*: Holladay JT, Jang A, Portney V., *Analysis of edge glare phenomena in intraocular lens edge designs*, J Cataract Refract Surg. 1999 Jun; 25(6):748-52.

[2] *See attached paper by the inventor*: Coroneo MT, Pham T, Kwok LS, *Off-axis edge glare in pseudophakic dysphotopsia*, J. Cataract Surg. 2003 Oct; 29 (10): 1969-73.

The angle of incidence used in the Portney citation results in a light focus which then causes the unwanted effects that are avoided by the lens of the present invention. It is thus apparent that Portney does not appreciate that the angle of incidence of light is the cause of unwanted optical effect. This is particularly apparent form a reading of the Portney paper where a statement made in relation to Figure 1 is that it shows "[t]he image of the glare source and the reflected glare image were formed on opposite sides of the peripheral retina." This is not true, as has been shown by the inventor of the present application.

Accordingly, the Portney lens does not solve the problem addressed by the present invention, i.e. preventing or reducing incident oblique light from striking the nasal perimeter of an IOL, passing to the nasal retina and causing pseudophakic dysphotopsia. Rather, it is aimed at providing a lens that reduces direct and indirect glare caused by light hitting the entire peripheral edge of an artificial lens.

Therefore, in view of the above, Applicants respectfully request that the rejection of Claims 1-4 and 12-18 be reconsidered and withdrawn.

Claims 5-7 over Portney and Brady

Claims 5-7 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Portney, in view of Brady et al., U.S. Patent Publication No. 2003/0144733 ("Brady"). Applicants respectfully traverse this rejection.

Brady discloses IOLs that have glare-reducing properties by incorporating features that reduce light reflecting off the edges of the IOLs. One such feature is the incorporation of light-absorbing materials and pigments (see paragraph 0123). The Examiner considers that the skilled

person would read the disclosure of Portney and consider it an obvious step to employ the light-absorbing materials taught by Brady in order to provide a lens that reduced glare by virtue of light absorbing materials.

Applicants respectfully disagree with the Examiner's combination of these references. Certain of the lenses taught by Brady have a very thin, peripheral edges (see edge numbered 42 in Figure 3), which are impregnated with color-absorbing material. As such, incident light is not absorbed or prevented from traveling posteriorly through the lens. rather, it is merely refracted over the pigmented peripheral edge of the lens (see Figure 6). Accordingly, these lenses also will not prevent light striking the nasal perimeter of an IOL and being focused onto sights in the nasal interior of the eye, and causing photic disturbances.

Indeed, one publication has examined lenses with frosted edges, such as those taught by Brady, and found that this frosting reduced, but did not eliminate the symptoms of dysphotopsia.[3]

Brady shows no appreciation of the focusing mechanisms described in the present application. The edge treatment described in Brady is marketed as OptiEdge™. These lenses are associated with dysphotopsia, so thus do not effectively reduce or eliminate oblique incident light photic disturbances in the eye.[4]

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[3] *See attached article:* Meacock WR, Spalton DJ, Khan S., *The effect of texturing the intraocular lens edge on postoperative glare symptoms: a randomized, prospective, double-masked study*, Arch Ophthalmol. 2002 Oct; 102(10): 1294-8.

[4] *See attached article*: Buehl w, Findl O, Menapace R, Rainer G, Sacu S, Kiss B, Petternel V, Georgopoulos M., *Effect of an acrylic intraocular lens with a sharp posterior optic edge on posteriors capsule opacification*, J Cataract Refract Surg. 2002 Jul; 28(7): 1105-11.

Brady also teaches intraocular lenses having an opaque, sharp peripheral edge, such as the one employed by an AcrySoft™ IOL product that is currently available. These lenses are also associated with dysphotopsia.[5]

Accordingly, it is apparent that the lenses taught by Brady do not function to reduce or eliminate oblique incident light photic disturbances in the eye, as they are unable to refract oblique incident light laterally or anteriorly, in order to reduce or eliminate light photic disturbances, unlike the intraocular lenses of the present application.

Therefore, in view of the above, Applicants respectfully request that the rejection of Claims 5-7 be reconsidered and withdrawn.

Claims 8 and 19 over Portney and Achatz

Claims 8 and 19 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Portney, in view of Achatz et al., U.S. Patent No. 4,813,955 ("Achatz"). Applicants respectfully traverse this rejection.

Achatz discloses bifocal lenses, with column 2, lines 24-39, describing an embodiment of these lenses where the "near range" zone of the lens is located adjacent to the wearer's nose (i.e. in the nasal region of the eye). The Examiner argues that the skilled person would take this information in order to modify the nasal portion of the Portney lens so that oblique incident light would be directed forward of the nasal retina.

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[5] *See attached study:* Tester R, Pace NL, Samore M, Olson RJ., *Dysphotopsia in phakic and pseudophakic patients: incidence and relation to intraocular lens type (2).* J Cataract Refract Surg. 2000 Jun; 26(6): 810-6; *and see also enclosed discussion letter: Potential Intraocular Lens Designs,* William M. Kirber, Eyeworld.

However, Applicants submit that one of ordinary skill in the art at the time of the presently-claimed invention would not have been motivated to combine Portney and Achatz as suggested by the Examiner because there is no suggestion of motivation for doing so in the references themselves or the knowledge available to one of ordinary skill in the art without resorting to impermissible hindsight. There is no teaching or suggestion in either Portney or Achatz that it is the passage of light through to the nasal retina that contributes to pseudophakic dysphotopsia. Indeed, this condition is not even discussed in either Portney or Achatz. Accordingly, Applicants submit that there would have been no rational basis for the skilled person, at the time of the present invention, to combine Portney and Achatz.

Therefore, in view of the above, Applicants respectfully request that the rejection of Claims 8 and 19 be reconsidered and withdrawn.

Claims 10 and 17 over Portney

Claims 10 and 17 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Portney. These claims recite an intraocular lens of the present invention wherein oblique incident light is in the range of 71-89 degrees. The Examiner notes that the angles of incident light disclosed in Portney "appear to fall" within this range. The Examiner states that the present application is silent as to the relevance of these angles of oblique incident light. The Examiner, however, is incorrect. It is clearly stated at least at page 11, lines 3-4 of the specification, that the inventors have found that oblique incident light is concentrated in an order of magnitude of 2.5 times the incident intensity, when the incident light is in the range of about 71-80 degrees. Furthermore, Example 1 describes how pseudophakic dysphotopsia symptoms in a patient were

studied for a range of incident light angles, and it was found that light was concentrated by a factor of 2.56 when the incident light was in a range of 71-89 degrees.

The Examiner states that the specification doesn't provide any reason why this range of incident light solves any problem. However, the Examiner has failed to note that it is incident light hitting the eye in this range of angles that is particularly problematic in causing pseudophakic dysphotopsia.

The incident light angles disclosed in Portney are randomly selected, and, while they may fall with in the range of 71-89 degrees, it is not stated that incident light of this particular angle range is the most problematic in causing photic disturbances in the eye. Furthermore, as discussed above, it is the vie of Portney that a 35 degree angle maximizes the intensity of the reflected glare image, as indicated in his publication by Holladay et al.[6] Accordingly, it is submitted that the skilled person would not consider it important to design a lens that minimizes the effects of oblique incident light within the particular angular range of 71-89 degrees.

Therefore, in view of the above, Applicants respectfully request that the rejection of Claims 10 and 17 be reconsidered and withdrawn.

Claims 9 and 11

Applicants note that while the Examiner lists Claims 9 and 11 as rejected on the cover sheet of the current Office Action, that the Examiner has failed to provide any basis or argument for such a rejection in the body of the Office Action. Therefore, Claims 9 and 11 must be treated

[6] *See above.*

as allowable. Applicants respectfully note that if the Examiner wishes to provide a rejection of Claims 9 and 11 that such a rejection must be provided in a new, non-final Office Action.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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AMENDMENTS TO THE DRAWINGS

Please add new Figure 7 as attached.

Attachment: New Sheet